EDITORIAL

Initial experience with PulseRider treatment for wide-necked bifurcation aneurysms

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In this article, Mukherjee and colleagues describe their initial experience using the PulseRider (Pulsar Vascular), a novel intravascular stent, to treat 10 bifurcation aneurysms. This study is only the second publication to include results of the device’s application at bifurcation points other than the basilar tip or carotid terminus. The authors report excellent short-term results after 6 months of follow-up, with complete occlusion of all treated aneurysms and no significant complications.

Since the advent of Gugliemi Detachable Coils in 1991, endovascular therapy for the treatment of ruptured and unruptured intracranial aneurysms has gained a solid foothold in the neurosurgical armamentarium. Initially, the scope of aneurysms that could be safely and effectively treated with endovascular techniques was relatively small compared to clipping procedures. With further technological development, the breadth of treatable aneurysms has increased; as a result, endovascular therapy has become the first-line therapy for the treatment of many intracranial aneurysms.

Wide-necked intracranial aneurysms, however, continue to pose challenges for the endovascular surgeon. Stent-assisted coiling and balloon remodeling techniques have been previously described and are effective in many instances but can be technically challenging, time consuming, and costly even in experienced centers. With the introduction of flow-diverting stents, a more diverse group of wide-necked aneurysms have been treated safely and effectively. However, placement of flow diverters across a large-vessel bifurcation is frequently avoided for fear of jailing the unstented daughter vessel. While Y-stent and X-stent techniques have been described and in use for many years, clearly development of more technologies to address wide-necked bifurcation aneurysms has been needed. The PulseRider is a novel intravascular stent-like device that is designed to replace the 2 stents necessary for typical Y-stent–assisted coil embolization of intracranial aneurysms. The device could more appropriately be considered an endovascular “buttress” specifically designed for this implementation, rather than a true vascular stent, as it is designed to maximize the metallic coverage at the neck of the arterial bifurcation with relatively little intraluminal metallic surface area otherwise. As such, it is well suited to support the coil mass within a bifurcation aneurysm.

The PulseRider is currently approved for use in Europe for all intracranial vascular bifurcation aneurysms and is actively undergoing clinical investigation in the United States under an FDA investigational device exemption for treatment of internal carotid artery terminus and basilar artery apex aneurysms (Adjunctive Neurovascular Support for Wide-necked Aneurysm Embolization and Reconstruction [ANSWER trial]; clinicaltrials.gov: NCT02312856). This study is slated for completion in the fall of 2016.

The published experience with the device is relatively limited currently. The first published report of its use was a case report from the summer of 2015. This was followed by a series of 15 patients from Europe and the US. The PulseRider has thus far been shown to be an effective support buttress for bifurcation aneurysm coiling, with 26 of 26 patients achieving a Raymond Class 1 outcome radiographically, and has reportedly been technically straightforward to use, with only 1 device failure reported. It requires only a single device (rather than 2 stents, as is conventionally required for Y-stenting) and therefore offers the promise of decreased fluoroscopy and anesthesia times for patients. Unlike traditional Y-stenting, this device does not require branch vessel catheterization and therefore reduces the theoretical risk of thromboembolism induced by manipulation of these smaller vessels.

The device comes in a range of sizes for different parent artery calibers, as well as Y- and T-configurations to...
accommodate a range of bifurcation anatomies. Still, concern must be raised as to whether the device can truly offer close wall approximation within the daughter vessels arising from the aneurysmal bifurcation point. We would expect thromboembolism to be more common with a device that is unable to closely approximate the vessel walls the way that true endovascular stents and flow diverters are capable of, and in fact, one thromboembolic complication (although asymptomatic) was reported by the authors of the current study and one was reported by Gory and colleagues. With this potential limitation in mind, the authors of the present study should be commended for their successful implementation at the middle cerebral artery and anterior cerebral artery bifurcations, which tend to form more variable, acute angles that we would anticipate to be difficult for conforming the device. It is perhaps for this reason that the ongoing clinical trial in the US has limited the indication for PulseRider to carotid and basilar termini.

Cautious optimism should be directed toward the future of the PulseRider device. Including the present study, the device has shown a very high success rate, with about 90% of treated aneurysms showing Raymond Class 1 coil occlusions; a relatively low risk of complications, with about 8% risk of thromboembolism (including asymptomatic thromboembolic complications); and only 1 device failure in the first 26 reported implementations. These numbers can be expected to improve as operator experience increases. While we are extremely optimistic about the safety and efficacy of this device at present, our optimism must be tempered by the lack of long-term follow-up. We must also continue to reevaluate the risks of utilization as implementation expands beyond the master surgeons and into typical use. As we look forward to further development of this and other devices designed to extend the reach of catheter-based approaches to intracranial aneurysm therapy, we must constantly reassess their utility and their risks with respect to the current standards of care. We eagerly anticipate the American debut of the PulseRider and expect that future experience will affirm its role for treatment of otherwise challenging wide-necked bifurcation aneurysms.

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References


Disclosures

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